

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

THIS DOCUMENT RELATES TO:

MDL NO. 2419
Docket No. 1:13-md-2419-RWZ

ALL SUITS NAMING THE NASHVILLE
HEALTHCARE

Case No. 1:13-cv-12731-RWZ
DENIS BROCK

Defendants

RULE 26 EXPERT DISCLOSURE

Denis S. Brock submits the following Rule 26 Expert Disclosures of an expert witness she may call to testify at the trial of this matter.

MATTHEW C. LEE, M.D., R.Ph., M.S.

I, Dr. Matthew C. Lee, am a practicing physician and pharmacist in Richmond, Virginia. I have a Master's of Science in Pharmacology and Toxicology. I have presented my research findings both nationally and internationally as well as published the results in peer reviewed journals. My research was funded by the National Institute on Drug Abuse (NIDA).

In the course of my training and clinical practice as a physician and pharmacist, as well as through my research experience, I am familiar with the sterile compounding of medications, pharmacology of such medications, and risks and consequences administering adulterated medications.

I have worked as a pharmacist since 1995. My pharmacy experience entails work in retail compounding pharmacies, and hospital pharmacies where sterile compounding is routine. I have worked as a hospital pharmacist since 2008. I have been a question writer for the National Boards of Pharmacy Licensure Exam (NABPLEX) for the past three years. I am currently licensed to practice pharmacy in Virginia, North Carolina and Kentucky. I currently own my own medical practice where I see adult patients with acute and chronic general medical conditions. I am licensed to practice medicine in Virginia.

I have been a Local Medical Examiner for the Commonwealth of Virginia since 2012. A Local Medical Examiner performs “views” on the bodies of person’s who died outside of the hospital setting, when circumstances do not require internal autopsies. Such would be the case for suspected overdoses, where cause of death can be determined through toxicological analysis of body fluid samples.

I am familiar with the recognized standards of acceptable professional practice in the general medicine, pharmacy, pharmacology and toxicology in Nashville, Tennessee and similar communities. I am familiar with the availability of services in Nashville and similar communities in 2012.

I have attached a copy of my curriculum vitae (CV) which is marked as Exhibit 1.

As grounds for my opinions, I am relying upon the pleadings, the medical records, depositions, studies and literature necessary for my opinions in this case. I have attached as Exhibit 2 to this disclosure, a list of the documents I relied upon to form my opinion.

During 2012, the Saint Thomas Outpatient Neurosurgical Center purchased the corticosteroid, methylprednisolone acetate (MPA), from New England Compounding Center (NECC).

I have reviewed the medical and billing records concerning the care and treatment of Denis Brock including injections of methylprednisolone acetate (MPA) at St. Thomas Outpatient Neurosurgical Center on July 23, 2012, and subsequent treatment for fungal meningitis. I have reviewed the depositions of John Culclasure and Debra Schamberg. It is my understanding that Ms. Brock was injected with adulterated MPA compounded by the New England Compounding Center in Boston, Massachusetts. I have reviewed information regarding the compounding practices of NECC. I have also reviewed information, in the form of discovery responses filed by St. Thomas Outpatient Neurosurgical Center and Saint Thomas Hospital, regarding their purchasing practices for compounded medications.

Denis Brock who has a past medical history significant for spinal stenosis, multiple sclerosis and hypothyroidism presented on February 4, 2013 to St. Thomas Hospital with a ten day history of headache and confusion. She was admitted with a strong suspicion of fungal meningitis due to history of having received a fungal contaminated epidural steroid injection in July of 2012. Ms. Brock underwent lumbar laminectomy on February 6, 2013 for suspected fungal meningitis. She did have a phlegmon and was treated with both IV and oral medications for presumptive fungal meningitis.

It is my opinion that St. Thomas Outpatient Neurosurgical Center, Saint Thomas West Hospital, Saint Thomas Network, Saint Thomas Health, Howell Allen Clinic, John Culclasure, M.D. and Debra Schamberg, R.N. failed to act with ordinary and reasonable care in accordance with the standard of care in Nashville, Tennessee, in the purchase of bulk, non-patient-specific, high-risk sterile injectable medications from the New England Compounding Pharmacy in June, July and August of 2012.

In addition to the above general statement concerning the failure of the Defendants to act within the standard of care then and there existing in Nashville, Tennessee for the procurement of compounding of drugs, I more specifically would give the following opinions with a reasonable degree of medical certainty.

1. Purchasing drugs from a compounding pharmacy are significantly more dangerous than purchasing drugs from an FDA approved manufacturer.

2. St. Thomas Outpatient Neurosurgical Center failed below the standard of care in purchasing from NECC by bulk rather than individual prescriptions, compounded drugs manufactured by NECC.

3. There were commercially available steroids for use in epidural spinal injections.

4. The St. Thomas Health System failed in its organization and regulation to educate and inform St. Thomas Outpatient Neurosurgical Center that they could not buy in bulk drugs from NECC and further, that they fail below the standard of care in ensuring that appropriately trained personnel were performing the job at St. Thomas Outpatient Neurosurgical Center of purchasing drugs pursuant to the appropriate standards of medical practice.

5. All the Defendants failed to ensure that trained personnel were aware of the laws, regulations and standards in buying drugs for the use of their patients including compounding drugs.

6. It was below the standard of care for St. Thomas Outpatient Neurosurgical Center to purchase steroids from a compounding pharmacy.

7. It was further below the standard of care to purchase said drugs without a patient specific prescription.

8. The employees and officers of St. Thomas Outpatient Neurosurgery Center were untrained in the buying of these drugs and should not have been permitted to make the decision to buy compounding drugs from NECC.

9. The Defendants and all of them involved in the buying of compounded drugs knew or should have known that medications purchased from NECC could only be acquired and dispensed pursuant to an individual patient specific prescription.

10. The Defendants and all of them involved were negligent and fell below the standard of care by not knowing or learning the rules applicable to pharmacy purchasing.

11. Further they were reckless in pursuing the buying of drugs from the compounding pharmacy, NECC without knowledge of the regulations, rules, standards or statutes and then putting those drugs in the bodies of the patients.

12. The actions of NECC should have raised a red flag regarding NECC's practices of producing compounded drugs and were negligent and reckless in ignoring these red flags.

13. It is my opinion that the above described conduct resulted in injury and death and would not have occurred and particularly injured Ms. Brock by causing her to contract meningitis.

Further, it is my opinion that the negligence of St. Thomas Outpatient Neurosurgical Center, Saint Thomas West Hospital, Saint Thomas Network, Saint Thomas Health, Howell Allen Clinic, John Culclasure, M.D. and Debra Schamberg, R.N. caused Denis Brock to suffer

injuries, including fungal meningitis and the symptoms, pain and suffering from this fungal meningitis medicine used to treat this fungal meningitis, which she would not otherwise have suffered.

I may also review other depositions, Affidavits or other information provided and/or filed in this case.

I am being compensated at the rate of \$500.00 per hour.

I have attached as Exhibit 3, a list of cases that I have testified in by deposition or trial for the past four years.

If called as an expert, I am expected to testify and offer a summary of testimony and opinions at trial and my opinions will be offered to a reasonable degree of medical certainty within the field general medicine, pharmacy, pharmacology and toxicology.


Matthew C. Lee, M.D., R.Ph., M.S.

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that a true and exact copy of the foregoing Rule 26 Expert Disclosure was served via U. S. Mail, postage pre-paid, to the following:

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This the 7 day of March, 2016.

GALLIGAN & NEWMAN
309 West Main Street
McMinnville, TN 37110
931-473-8405



Michael D. Galligan #3181
(Attorney for Denis Brock)

EXHIBIT 1 - CURRICULUM VITAE (CV)

4/3/2013

CURRICULUM VITAE



MATTHEW C. LEE, MD, RPH, MS

PHYSICIAN, PHARMACIST, PHARMACOLOGIST & TOXICOLOGIST

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Suite A-5

Richmond, VA 23226

Contact: 804.358.1492 Fax: 804.358.1491

eMail: mlee@eLEETePhysicians.com

I. EMPLOYMENT



Physician. eLEETe Physicians, LLC, Primary Care Practice. Primary care physician (PCP). General Practice.



Pharmacist. Parallon Solutions. Provide patient care activities to ensure safe and effective drug therapy. Accurately enter orders in the computer and timely manner. Screen for drug interactions, allergies, or duplications, appropriate diagnosis, renal and liver function prior to order entry. Investigate and report adverse drug events and medication incidents. Review and interpret all physician orders received using patient profiles. Monitor for incompatibilities, concentration and rate of intravenous drugs. Assess orders for age specific appropriateness from neonatal through geriatric. Dissemination of drug information.



Physician. Apple Mobile Medical. Occupational Health Physician at TEVA Pharmaceuticals. Perform annual Employee Health Surveillance and pulmonary assessments on employees required to wear respirators. One week per year.

II. WORK HISTORY:



Physician. United States Department of Defense, Military Entrance Processing Station (MEPS), Fort Lee Virginia. Physician, perform physicals on new military recruits to determine medical qualification as required for entrance into any branch of the U.S. Military as defined by the protocols established the U.S. Department of Defense.



Physician. Apple Mobile Medical Occupational Health. Perform Personal Health Assessments on Pre- and Post- deployment soldiers in the United States National Guard.



Physician. Locum Tenens in Occupational Health and Family Practice for Jackson and Coker.

Zelda West Johnson, MD and Associates Family Practice- Physician in Family Practice.

Pharmacist, Walnut Hill Pharmacy, Petersburg, VA

Pharmacist; Poplar Springs Hospital; Petersburg, VA.

Pharmacist for Wal-Mart pharmacy, as needed throughout Virginia

Pharmacy Manager; Wal-Mart Pharmacy; Tarboro, NC.

Lab Technician; Medical College of Virginia, Department of Pharmacology; Richmond, VA.

Pharmacist; Prince George Pharmacy; Prince George, VA.

III. EDUCATION AND TRAINING



Undergraduate - Barton College (previously Atlantic Christian College).
September 1988 – May 1990.



Undergraduate - Virginia Commonwealth University, **Bachelor's of Science in Chemistry**. August 1992.



Professional - Medical College of Virginia, School of Pharmacy,
Bachelor's of Science in Pharmacy (B.Pharm). May 1995.



Graduate - Virginia Commonwealth University Department of Pharmacology/Toxicology. **Master's of Science in Pharmacology and Toxicology**. September 1997 – August 1999.

Thesis: The Role of several kinases in mice tolerant to delta-9 Tetrahydrocannabinol.



Doctoral - Virginia Commonwealth University School of Medicine, **Doctor of Medicine (M.D.)**. May 2004.



Post-Doctoral - Internship in Internal Medicine, Virginia
Commonwealth University Medical Center. July 2004 – June 2005.

IV. CERTIFICATIONS AND LICENSURE



Musculoskeletal Exam and Treatment Techniques, American College of Occupational and Environmental Medicine.



Medical Review Officer, Certified by American College of Occupational and Environmental Medicine.



Commonwealth of Virginia, license to practice medicine and surgery.



Commonwealth of Virginia, license to practice pharmacy.

V. APPOINTMENTS



National Association of Boards of Pharmacy Licensure Exam (NABPLEX) question writer.



National Academy of Sciences, Science & Entertainment Exchange Consultant.



CBS *Criminal Minds*.





Journal of Clinical Pharmacology Peer Review Board.




DynaMed Editorial Team Reviewer.
<http://www.ebscohost.com/dynamed>.

VI. PUBLICATIONS AND RESEARCH PRESENTATIONS

 *DynaMed* Editorial Team. Lee, M (Reviewer). Neuroleptic Malignant Syndrome. Last updated 2012 05 01. Available from *DynaMed*: <http://www.ebscohost.com/dynamed>.

 *DynaMed* Editorial Team. Lee, M (Reviewer). Paralytic Shellfish Poisoning. Last updated 2012 06 21. Available from *DynaMed*: <http://www.ebscohost.com/dynamed>.

 *DynaMed* Editorial Team. Lee, M (Reviewer). Anti-Cholinergic Poisoning. Last updated 2012 11 27. Available from *DynaMed*: <http://www.ebscohost.com/dynamed>.

Assessment of Marijuana Intoxication. Matthew C. Lee, MD, RPh, MS. October 4th, 2010. www.HGExperts.com, and www.ExpertPages.com.



Quantum Free Will. Matthew Lee. *New Scientist*. September 1st-7th; 195(2619):25.



The Role of Several Kinases in Mice Tolerant to Delta-9 Tetrahydrocannabinol. M. Lee, D. Stevens, S. Welch. *Journal of Pharmacology and Experimental Therapeutics*. 2003 May; 305(2):593-9. <http://jpet.aspetjournals.org/content/305/2/593.full.pdf+html>

The Effects of Blocking Several Kinases in Mice Tolerant to Δ 9-THC. Matthew C. Lee, David L. Stevens and Sandra P. Welch. Virginia Academy of Sciences May 1999.

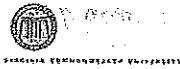


Reversing Δ 9-THC Antinociceptive Tolerance by Inhibiting the Phosphorylation of the CB1 Receptor. Matthew C. Lee, David L. Stevens and Sandra P. Welch. FASEB, 1999.

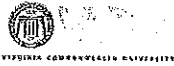


The Role of Several Kinases in Mice Tolerant to Δ 9-THC. Matthew C. Lee, David L. Stevens and Sandra P. Welch. International Cannabinoid Research Society, 1999.

VII. HONORS AND AWARDS



Distinguished Service Award. Virginia Commonwealth University.



University Leadership Award. Virginia Commonwealth University.



Local Association President's Award. Virginia Pharmacist's Association.



Professionalism Award. American Pharmaceutical Association/McNeil Consumer Products.



ALLEN & HANBURY'S
Pharmaceuticals Division
of GlaxoSmithKline

Allen and Hanbury's Pride in Pharmacy Scholarship Award.

VIII. VOLUNTEER ACTIVITIES

Physician Volunteer, Fan Free Clinic, Richmond, VA.

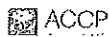
Foundations of Clinical Medicine Assistant Instructor.

Professionalism Workshop Group Leader.

Virginia Pharmacist's Association Board of Directors.

Speaker's Bureau for the Pitt County (North Carolina) AIDS Service Organization (PICASO).

IX. PROFESSIONAL MEMBERSHIP



American College of Clinical Pharmacology



American College of Occupational and Environmental Medicine



American Medical Association



American Pharmacists Association



Medical Society of Virginia



American Society of Pharmacy Law

Richmond Academy of Medicine

EXHIBIT 2 - LIST OF DOCUMENTS REVIEWED

List of Documents Reviewed by Matthew C. Lee, M.D., R.Ph., M.S.
In support of Rule 26 Expert Disclosure

1. Pleadings
2. Medical and billing records of St. Thomas Outpatient Neurosurgical Center on July 23, 2012 and subsequent treatment for fungal meningitis.
3. Depositions of Dr. John Culclasure and Debra Schamberg
4. Studies and literature
5. Information regarding the compounding practices of NECC
6. Discovery responses filed by St. Thomas Outpatient Neurosurgical Center and Saint Thomas Hospital regarding their purchasing practices for compounded medications
7. Report of Opinions of James L. Gray, III, PharmD, MBA

EXHIBIT 3 - LIST OF CASES DR. LEE HAS OFFERED TESTIMONY

List of Cases Dr. Matthew C. Lee, M.D., R.Ph., M.S. Has
Offered Testimony In support of Rule 26 Expert Disclosure

Testimony Case Summary

December 17, 2015

	Law firm/Attorney	Date	Location	Plaintiff or Defense	Case	Outcome	Circumstances
1.	Arnold, Torado, and Welch. Columbus, OH Jerry Torado, Esq 2075 MarbleCliffOffice Park Columbus, OH43215	3/12	Columbus, OH	D	Miller v Andrews	Settled (Deposed)	?HIT, DVT, subtherapeutic INR on Coumadin, Rx Lovenox. ?Whether Lovenox was contributing factor for worsening Lower Ext thrombus due to hx of HIT, and resulting amputation.
2.	Harris, Matthew & Crowder, PC. (CalSpencer, Esq.)	5/12	Lunenburg, VA	D	Commonwealth of Virginia v. Alan Cryderman	(Criminal) Testified at sentencing hearing.	Oxycodone-alcohol effects on body, mind and memory.
3.	Rappoport Law Office (Michael Teich, Esq.)	4/12	Chicago, Il	P	Martynowicz v. Walgreen's	Settled 9/13. Deposed 7/10/12	Misfill Synthroid, resulting in hypothyroid during 2 nd trimester of pregnancy, cognitive developmental issues.
4.	Snook &Haughey Charlottesville, VA LloydSnook, Esq. LouDiamond, Esq.	1/9/13	Charlottesville, VA	D	USA v. Stephen McFadden (Federal)	(Criminal case) Jury Trial	"Bath Salts", Substantially similar, Analogs, Controlled Substance Act. Methylone, MDPV, 4-MEC.
5.	Rod Sager Law Offices Rod Sager, Esq. Richmond, VA	6/12	Richmond, VA	P	Martin v. Rubin	Deposed Settled December 2012	NSAIDS, Corticosteroids, Tobacco (Smoking), on wound healing, and non-union.
6.	Barnes and Cohen , PA (GlenE.Cohen, Esq.)	6/11	Chatam County, GA	P	Roosevelt Johnson, Jr. v. State of Georgia and Gateway Behavioral Health Services,	Deposed 9/12 Settled.	NMS secondary to Haldol decanoate injection, secondary UEDVT.
7.	Jordan, Coyne &Savits Deborah Wheilan, Esq. Fairfax, VA		Vienna, VA	D	Franco v. Metrocall	Deposed 3/13 Settled	Reasonableness of medications. Medication costs, projected costs.

	Law firm/Attorney	Date	Location	Plaintiff or Defense	Case	Outcome	Circumstances
8.	Gardner, Maupin, Sutton & Haney, P.C. Mark Gardner, Esq. The Professional Building PO Box 129 Spotsylvania C.H., VA22553	2/13	Stafford County, VA	D	Commonwealth of Virginia v. Karen E. Walls	(Criminal) Jury trial, February 14 th , 2013. Expert - Pharmacology and toxicology relative to medications and impairment. Medical doctor relative to SVT and Pain Management. Mistrial – Deadlocked jury. No retrial/Chgs dropped.	Expert in Internal Medicine, Cardiology, Pharmacology/Toxicology. SVT episode. Soma, oxy, diaz for chronic pain. Appeal of DUI conviction.
9.	Stallings, Bush & Randall, P.C. Sonny Stallings Va.Beach, Va.	9/24/13	Virginia Beach, VA	D	Comm. Of VA vs. Jocelyn Anderson.	(Criminal) Bench trial. DUI Charges dismissed. Involuntary Intoxication.	Accepted as pharm/tox expert, medical doctor, pharmacist, MRO. DUI – Involuntary intoxication. Diphenhydramine (hair sample) and etoh. Date rape drug.
10	McEachin and Gee Donald McEachin, Esq. Priscilla Woody, Esq.	10/31/13	Richmond, VA	P	Snedden v. Do.	Jury trial (Civil) Personal Injury, auto accident. Def was drinking alcohol.	Accepted as Medical and Toxicology Expert.
11	Klabugh Pfund & Messersmith EricAndrew, Esq.	3/2013	Roanoke, VA	D	Franklin v. Kmart, Lynchburg General Hospital	Deposed November 2013	ESRD, COPD, rec'd altace instead of pred. development of ischemic bowel.
12	Pullin, Fowler, Flanagan, Brown & Poe PLLC Linnsey Amores, Esq.	3/2014	Charleston, WV	D	Unik v. RxByTel	Deposed May 2014 (Settled)	Wrongful death secondary to fentanyl patch. Question of dose interpretation as written by MD, as well as causation.

	Law firm/Attorney	Date	Location	Plaintiff or Defense	Case	Outcome	Circumstances
13	Habush Habush & Rottier S.C. D. James Weis, Esq.	3/2014	Wausau, WI	P	Buettner v. Aspirus Wausau Hospital	Deposed July 2014 Settled December 2014	Inadvertent administration of epinephrine IV vs. subq or IM as indicated. Causation.
14	Shapiro, Lewis Appleton & Duffan P.C. James Lewis, Esq. Virginia Beach, VA	10/2014	Rockville, NC	P	Alsup v. Carolinas Medical Center/ Cabarrus ER Assoc.	Deposed 11/4/2014	Fentanyl patch overdose. Narcan via EMS. New patch applied in ER, dc'd after 4 hours. Found dead next day. Cause of death Fentanyl OD.
15	Albo & Oblon, LLP Dave Albo Springfield, VA	11/6/14	Fairfax, VA	D	Comm of Va vs. Cruz.	(Criminal) Trial 11/6/2014 Null Processed	THC metabolite, (THC-COOH) basis for DUI.
16	Stallings, Bush & Randall, P.C. Sonny Stallings Va Beach, Va.	4/10/14	Virginia Beach, VA	D	Comm. Of VA vs. Angela Abby	(Criminal) Bench trial 4/10/14. Charges dismissed	DUI – Involuntary Intoxication. Diphenhydramine (hair sample) and etoh. Date rape drug.
17	Frost Brown Todd LLC Anthony Overholt, Esq. Indianapolis, IN	7/2014	Indianapolis, IN	D	Flannery Estate v. City of Indianapolis	Deposed 10/20/2014 Settled	Death in custody, post-mortem tox: etoh, synthetic cannabinoids.
18	Spence Law Firm Regina Guy, Esq. Memphis, TN	6/2014	Memphis, TN	P	Mayfield v Methodist University Hosp, Memphis	Deposed 11/11/2014	Perc/Dilau/Xanax Resp failure in pt with IPF/SLE who devel pneu.
19	Cantor, Stoneburner, Ford Grana & Buckner. Bellamy Stoneburner, Esq. Richmond, VA	11/13	Richmond, VA	P	Fountain v MEDERVA	Deposed 1/20/2015 Settled	Ropivacaine overdose, caudal epidural, 21 month old, premie, FTT.
20	Patrick, Beard, Schulman & Jacoway, P.C. Michael Anderson, Esq. Chattanooga, TN	1/14	Rhea, TN	P	Ballard v. ECC	Deposed 2/9/2015	Peds SJS, Septra, MRSA prophylaxis.

	Law firm/Attorney	Date	Location	Plaintiff or Defense	Case	Outcome	Circumstances
21	Belsky, Weinberg & Horowitz, L.L.C. Thomas Glancy, J., Esq. Baltimore, MD	1/14	Finksburg, MD	P	Karon Moore v. Rite Aid	Deposed 2/13/2015	Chloroquine for malaria prophylaxis dispensed with directions to take daily.
22	Hall and Sethi Gobind Sethi, Esq.	6/14	Reston, VA	P	Stirk v Wilson	Deposed 07/23/2015	Coumadin dosing error, subsequent stroke.
23	Prosecution Services Bureau State of Montana Mary Cochenour, Esq State Prosecutor Helena, Montana	9/15	Helena, MT	Prosecute	State of Montana v. Joseph Campbell	(Criminal) Testified at hearing 9/1/2015	Homicide, post-mortem tox with THC. Effects of THC.
24	The Law Office of John A. Blazer. John Blazer, Esq Fairfax, VA	3/14	Fairfax, VA	P	Steinhardt v. Giant Pharmacy	Deposed 9/25/2015	Pharmacy standard of care regarding prescription counseling, vaccinations and informed consent.
25	Marsh, Rickard & Bryan Roger Lucas, Esq. Birmingham, AL	8/15	Jefferson County, AL	P	Jones v. David's Discount Pharmacy	Deposed 10/20/2015	Rx misfill, methadone for methimazole. Methadone toxicity. Cause of death.
26	The Edwards Law Firm Mark Edwards, Esq.	12/12	Tulsa, OK	P	Persinger v Jaiswal Clinic, Lindsay Pruett, PA.	Deposed 11/3/2015	Coumadin – Bactrim interaction, lack of monitoring.
27	The Clifford Law Firm Keith Hebeisen, Esq. Chicago, IL	2/15	Chicago, IL	P	Vandelinder v Northwestern Memorial Hospital	Deposed 11/16/2015	Foscarnet overdose/toxicity, renal failure, pancytopenia, immunosuppression.
28	The Spence Law Firm Regina Guy, Esq. Memphis, TN	9/15	Memphis, TN	P	McGill v Methodist Hospital	Deposed 11/20/2015	Sumatriptan administration, indications, pharmacology, headache diagnosis